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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,402	08/03/2001	Peter Hofert	SCH 1808	9208
23599	7590	01/26/2004	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			MAIER, LEIGH C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,402

Applicant(s)

HOFERT ET AL.

Examiner

Leigh C. Maier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 8 and 10-22 is/are pending in the application.
- 4a) Of the above claim(s) 8, 12 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 10, 11, 13-20, and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

Claims 6 and 9 have been canceled. Claims 1-5, 7, and 10-16 have been amended. Claims 17-22 have been added. Claims 1-5, 7, 8, and 10-22 are pending. Claims 8 and 12 were previously withdrawn pursuant to a restriction requirement. Newly added claim 21 depends from claim 12 and is likewise withdrawn. Any rejection or objection or rejection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 7 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 depends from canceled claim 6, thus rendering the claim vague and indefinite.

Claim 18 recites the limitation "said precipitation reaction." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 U.S.C. § 103

Claims 1, 4, 5, 7, 10, 15, and 16 are again rejected under 35 U.S.C. 103(a) as being unpatentable over BACKENSFELD et al (US 5,798,338), as set forth in the previous Office action. Newly submitted claim 18 is also included in this rejection.

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The invention is as set forth in the previous Office action. Claim 18 is drawn to preparation comprising a co-precipitation reaction.

Applicant's arguments filed 30 October 2003 have been fully considered but they are not persuasive.

Applicant argues that the gestagens mentioned by BACKENSFELD do not possess a 14,17-C₂-bridge, whereas the claimed gestagens do have such a bridge and have an α -hydroxyketone side chain at the 17 position.

BACKENSFELD is a general teaching that steroidal sex hormones are subject to oxidative degradation that can be avoided by complexation with cyclodextrins. The reference specifically suggests the use of other steroidal sex hormones having a 14,17-C₂-bridge, so one of ordinary skill would be motivated to prepare complexes with similarly structured steroids to decrease oxidation with a reasonable expectation of success. The examiner further notes that the claims do not require an α -hydroxyketone side chain at the 17 position.

Applicant further argues that BACKENSFELD provides no teaching to motivate the skilled artisan to stabilize gestagens to prevent/reduce acyloin rearrangements of the gestagen. It is noted that the features upon which applicant relies (i.e., prevention/reduction of acyloin rearrangements) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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Claims 1-5, 7, 10, 11, and 13-16 are again rejected under 35 U.S.C. 103(a) as being unpatentable over BACKENSFELD et al (US 5,798,338) in view of SCHOLLKOPF et al (WO 96/20209), as set forth in the previous Office action. Newly added claims 17-20 and 22 are included in this rejection.

The invention is as set forth in the previous Office action. Various dependencies have been changed. Newly added claim 22 is drawn to a combination consisting of a gestagen of formula I and a cyclodextrin.

Applicant's arguments filed 30 October 2003 have been fully considered but they are not persuasive. The only additional argument presented was that SCHOLLKOPF does not correct purported deficiencies of BACKENSFELD. The arguments regarding BACKENSFELD have been addressed above.

With regard to new claims 17 and 20, SCHOLLKOPF specifically discloses the compound recited in claim 20, which has $R^{21} = \text{hydroxy}$. See page 6, line 14. It would have been obvious to one having ordinary skill at the time the invention was made to use any of these compounds in combination with the estrogens and cyclodextrin to prepare a medicament administered for birth control, as set forth in the previous Office action.

With regard to new claims 18 and 19, the claims are drawn generally to the preparation of a gestagen/cyclodextrin complex comprising a precipitation step. Claim 19 adds the limitation of adding an ethanolic solution of the gestagen to an aqueous solution of cyclodextrin to effect precipitation of the product. General precipitation has been addressed in the previous Office action. BACKENSFELD teaches the preparation of clathrates of steroidal sex hormones by adding the steroid, dissolved in an appropriate solvent such as ethanol, to an aqueous solution of

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the cyclodextrin, thereafter filtering the resulting precipitate. See col 2, lines 36-37 and lines 40-44. It would be within the scope of the artisan to adapt this process to prepare a cyclodextrin complex of a gestagen, such as the ones disclosed by SCHOLLKOPF with a reasonable expectation of success.

With regard to claim 22, the claim is drawn to a combination *consisting* of a gestagen of formula I and a cyclodextrin, thereby excluding other components. As discussed above, BACKENSFELD is a general teaching with respect to the use of cyclodextrins to stabilize steroidal sex hormones, including gestagens. This reference does not specifically disclose the gestagens of formula I. These gestagens are disclosed by SCHOLLKOPF. It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare a complex consisting of a cyclodextrin and a gestagen disclosed by SCHOLLKOPF. Given the teaching of BACKENSFELD, one of ordinary skill would expect that the gestagens disclosed by SCHOLLKOPF would also be subject to degradation as discussed in BACKENSFELD. Therefore the artisan would be motivated to prepare such a complex in order to stabilize these gestagens with a reasonable expectation of success.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's hours, phone & fax numbers

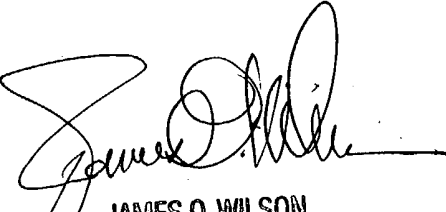
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (703) 308-4624, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
January 22, 2003


JAMES O. WILSON
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